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(54) ANASTOMOSIS DEVICE AND METHOD

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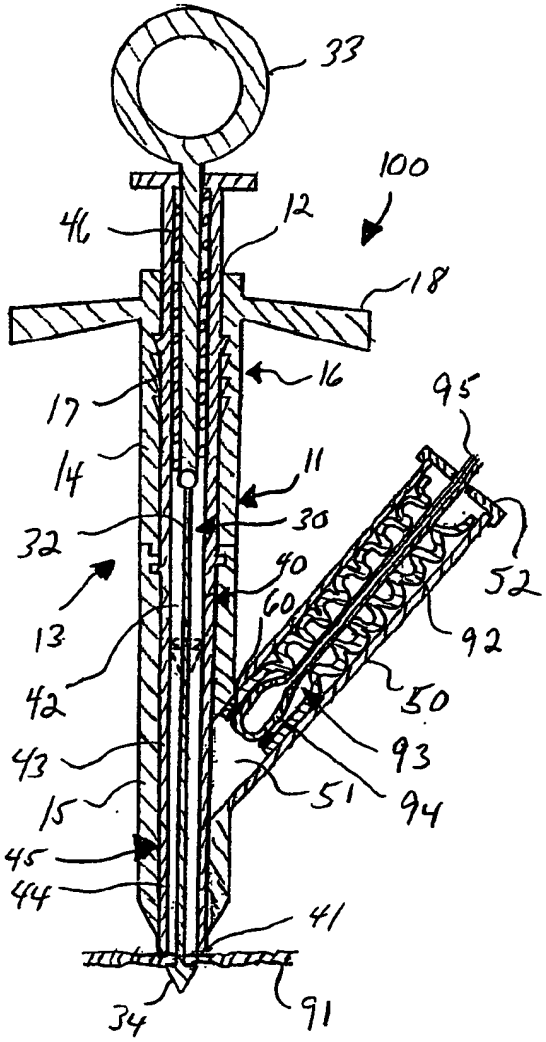
(57) ABSTRACT

The invention is a device for anastomosis of a vein graft to an aorta, wherein the device is used for creating a circular hole in the aorta wall, occluding the hole to prevent blood loss and providing a guide for insertion or placement of the vein into the hole in the aorta wall. The device has an elongated main body housing a punch mechanism, the punch mechanism having a disk-shaped punch head and a tubular cutting sleeve, which in conjunction act to remove a circular plug from the aorta wall, wherein the punch head is retractable relative to the cutting sleeve, with the cutting sleeve remaining in the aorta wall to prevent blood loss, and a lateral shaft having an internal bore communicating with the main bore of the cutting sleeve, whereby a vein graft can be introduced into the main bore and through the aorta wall.



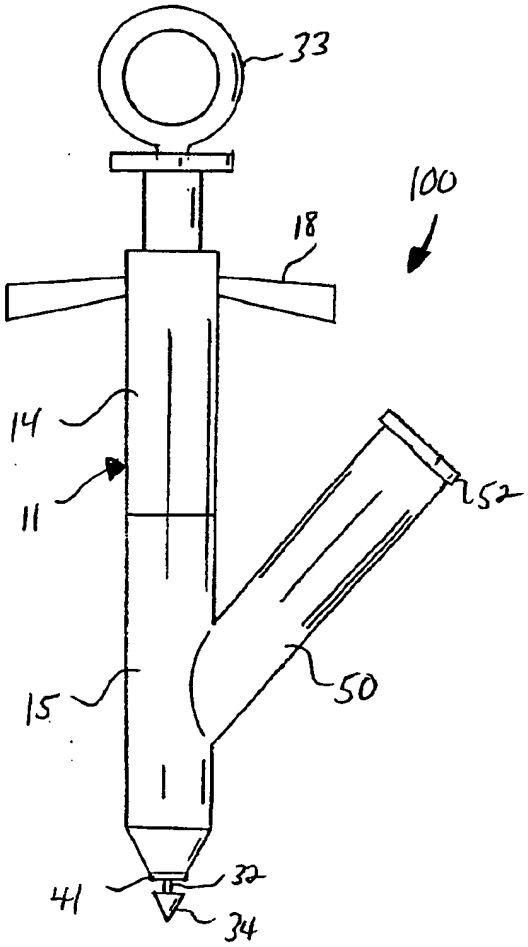

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FIG. 1

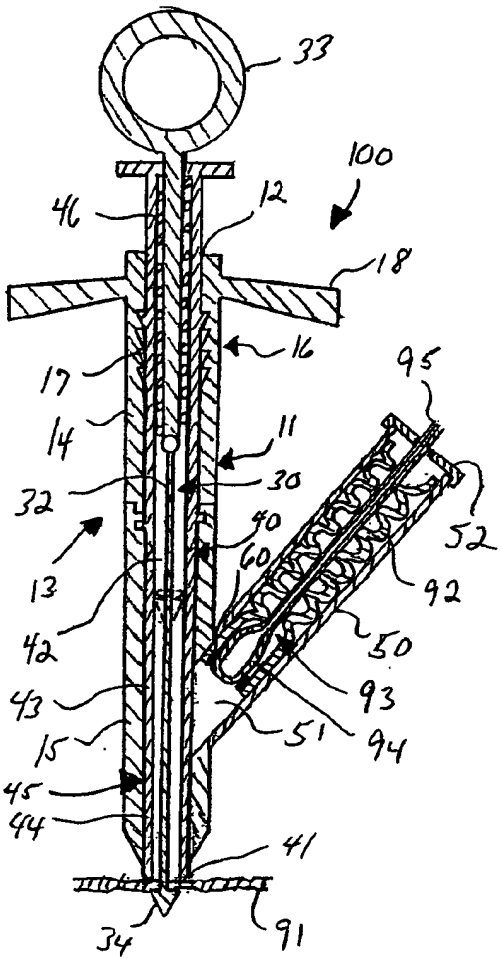
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FIG. 2

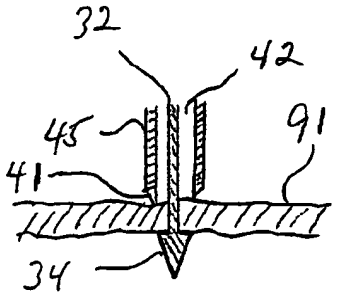

FIG. 3

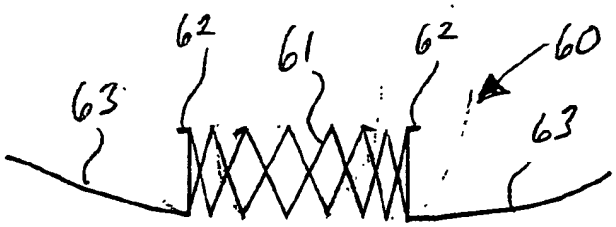

FIG. 5

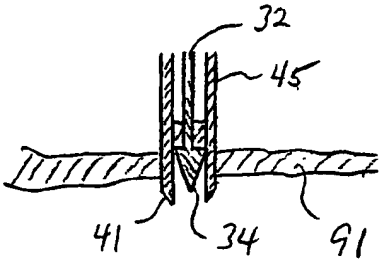

FIG. 4

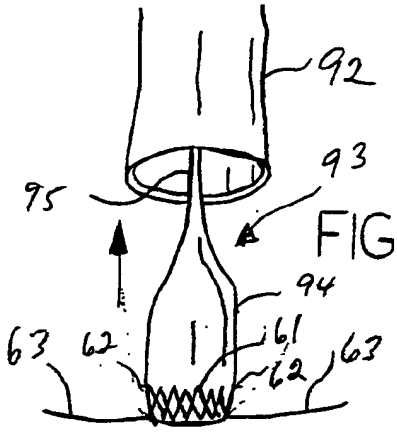

FIG. 6

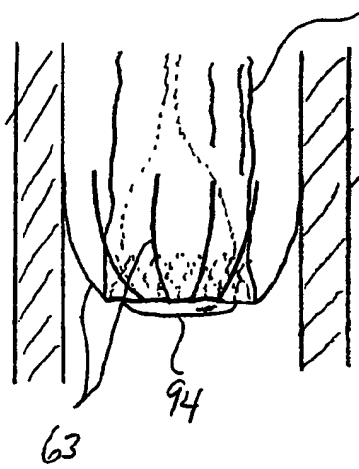

FIG. 7

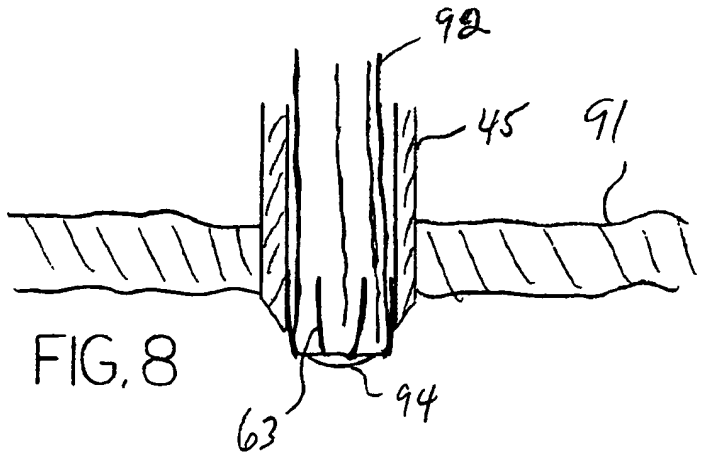

FIG. 8

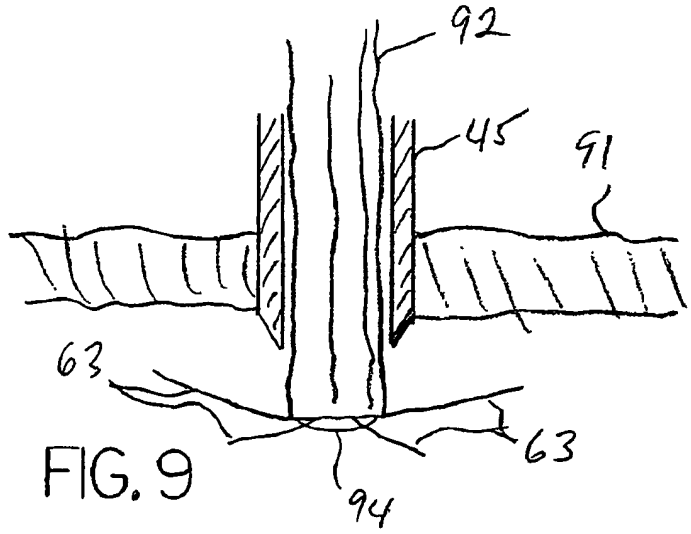

FIG. 9

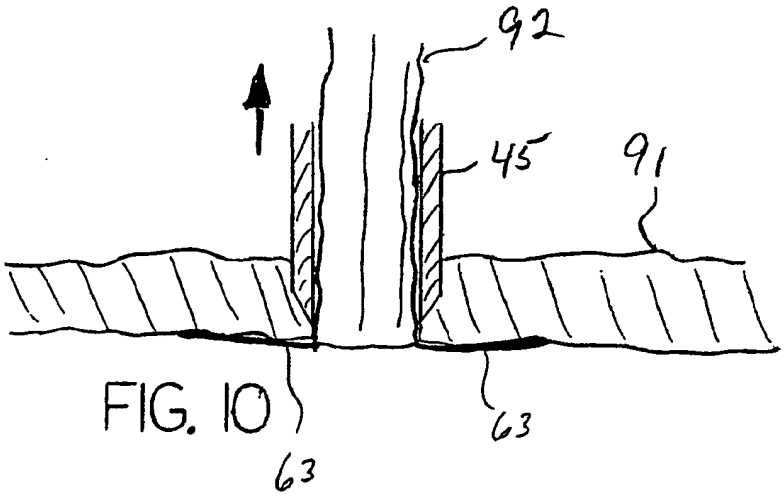

FIG. 10

ANASTOMOSIS DEVICE AND METHOD

BACKGROUND OF THE INVENTION

[0001] This invention relates generally to the field of devices and methods used in performing anastomosis, i.e., the joining of a hollow or tubular organ to another hollow or tubular organ, and in particular to such devices used in the surgical joining of a vein graft to the aorta wall.

[0002] In coronary bypass surgery, a blocked or damaged segment of an artery is bypassed by attaching a vein graft to the aorta above the blocked point, such that blood flow is routed through the vein graft and around the blockage. In order to attach the graft, a hole must be created in the aorta wall, which may be formed by use of a scalpel but is preferably accomplished using a punch device in order to create a circular opening rather than a slit, as the circular opening is less likely to tear. The punch device typically comprises a sharp cone or bladed disk which creates a small slit in the aorta wall, through which the entire disk is passed. The disk is mounted onto a thin shaft, which is coaxially received by a tubular sleeve member, the end of which is provided with an annular cutting edge or rim. With the aorta wall now disposed between the disk and the sleeve, either the disk is withdrawn into the sleeve or the sleeve is advanced to surround the disk. This shearing operation cuts a circular opening in the aorta wall, and the plug cut from the wall is entrapped within the sleeve and disk when the punch device is removed.

[0003] It is necessary to temporarily occlude the opening in the aorta wall in some manner to prevent excessive loss of blood during the anastomosis procedure. In a most basic technique, the surgeon attempts to cover the opening with a finger, but this method is less than optimal. Use of the finger limits the surgeon's dexterity, as it is much easier to attach the vein graft if the surgeon has both hands free and does not need to concentrate on excessive blood loss. Alternatively, a surgical clamp may be applied across the aorta upstream of the opening, which reduces the necessity for the surgeon to rush through the attachment procedure and allows the surgeon free use of both hands, but this technique is problematic in that it stops all blood flow for the period of time necessary to complete the graft, and the pressure from the clamp may damage the aorta or may result in the release of plaque or other debris into the blood stream.

[0004] It is an object of this invention to provide an anastomosis device and a method of use for same. The device operates initially as a punch to create a well-defined circular opening in the aorta wall by removing a plug of wall material, then occludes the hole in the aorta wall after creation of the circular opening to prevent excessive blood loss during attachment of the vein graft, and subsequently provides a conduit for guidance of the vein to and into the hole in the aorta wall. In conjunction with a specialized anchoring means affixed to the end of the vein graft, the vein is inserted into the hole in the aorta wall and permanently connected without the need for extraneous suturing. These objects as well as other objects of the invention not expressly set forth above will be disclosed in the description to follow.

SUMMARY OF THE INVENTION

[0005] The invention is a method and system for anastomosis of a vein graft to an aorta comprising a novel instrument or device which creates a circular hole in the aorta wall, occludes the hole to prevent blood loss and provides a guide for insertion of placement of the vein into the hole in the aorta wall. The device comprises in general an elongated main body defining a main bore and housing a punch mechanism, the punch mechanism comprising a disk-shaped punch head and a tubular cutting sleeve, which in conjunction act to create, remove and retain a circular plug from the aorta wall, means to retract the punch head relative to the cutting sleeve such that the cutting sleeve remains in the aorta wall to prevent blood loss, an obliquely connected lateral shaft having an internal bore communicating with the main bore of the cutting sleeve, and means to retract the punch head and a portion of the cutting sleeve in the proximal direction to expose the lateral shaft opening into the main bore, whereby a vein graft can be introduced into the main bore and through the aorta wall by passing the graft through the lateral shaft. A portion of the cutting sleeve remains disposed in the aorta wall to prevent blood loss during the insertion of the vein graft. The anchoring means for the vein graft preferably comprises an expandible annular wire lattice having short radial projections to secure the lattice in the interior of the vein and longer, flexible prongs which are compressed against the outer wall of the vein while resident within the lateral shaft and during passage through the cutting sleeve portion of the device, but which automatically expand radially to prevent withdrawal of the vein from the aorta wall after the anchoring means is fully inserted and extended from the distal end of the cutting sleeve. The anchoring means is secured to the vein prior to insertion into the lateral sleeve, and is advanced through the lateral shaft and cutting sleeve bore by use of a balloon catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] **FIG. 1** is an exterior view of the anastomosis device.

[0007] **FIG. 2** is a cross-sectional view of the anastomosis device inserted into the aorta wall, showing the vein graft in position in the lateral shaft.

[0008] **FIGS. 3 and 4** show the punch mechanism in action forming the hole in the aorta wall.

[0009] **FIGS. 5 through 7** show the method for securing the vein to the aorta wall using the anchoring means.

[0010] **FIG. 8** is a view similar to **FIG. 2** showing separation of the housing for retraction of the punch assembly after the hole has been created in the aorta wall.

DETAILED DESCRIPTION OF THE INVENTION

[0011] With reference to the drawings, the invention will now be described in detail with regard for the best mode and the preferred embodiment. In general, the device comprises means to produce an opening in an aorta wall, means to seal the opening during the anastomosis process to preclude excessive blood loss, and means to receive and advance a vein graft through the device for attachment of the vein graft to the aorta wall.

[0012] As shown in **FIGS. 1 through 4** and **8**, the anastomosis device **100** comprises an elongated housing **11** having a central bore **12** which coaxially receives a cutting

sleeve assembly **40** and a punch assembly **30**, where the cutting sleeve assembly **40** and the punch assembly **30** are movable in the axial direction relative to the housing **11**. The housing **11** is divided into a proximal portion **14** and a distal portion **15** to define a punch retraction means **13**, shown as comprising the proximal and distal portions **14** and **15** joined by connection means **19**, such as a male and female threading or a key and slot combination, such that rotation of one portion relative to the other allows the two portions **14** and **15** to be separated, such that proximal portion **14** along with punch assembly **30** and the proximal portion **43** of cutting sleeve **45** can be withdrawn relative to the distal portion **15** and the distal portion **44** of cutting sleeve **45**, as seen in **FIG. 11**. A sleeve advancement means **16**, shown as a rachet mechanism **17**, allows the cutting sleeve **45** to be advanced relative to the punch head **34** to create a hole in the aorta wall **91**. A lateral shaft **50** is joined at an acute angle to the housing **11**, the lateral shaft **50** having a lateral bore **51** covered on one end by a removable cap **52** and open on the other end such that it communicates with the central bore **12** of housing **11** when the proximal portion **43** of sleeve **45** is withdrawn along with the punch assembly **30**.

[0013] The punch assembly **30** comprises a shaft **33** bounded on the proximal end by a handle **33** and on the distal end by a punch head **34**, the punch head **34** having a pointed or bladed distal portion **34***a* formed with a disk-shaped proximal end **34***b*. The cutting sleeve assembly **40** comprises a tubular cutting sleeve **45** defining an axial bore **42** with an annular cutting rim **41** which acts in cooperation with punch head **34**, as shown in **FIGS. 3 and 4**, to cut a hole into the aorta wall **91** by removing a plug of wall material, the plug being retained within the cutting sleeve **45** behind the proximal end **34***b* of punch head **34**. The cutting sleeve **45** comprises a separable proximal portion **43** and a distal portion **44**. A spring member **46** maintains the cutting sleeve **45** in the retracted position until it is depressed by the surgeon to advance the annular cutting rim **41** past the punch head **34**. After the hole has been made in the aorta wall **91**, the distal portion **15** and the proximal portion **14** of the housing **11** are separated and the punch assembly **30** and sleeve proximal portion **43** are retracted, such that the punch head **34** and distal end of the sleeve proximal portion **43** are now positioned proximal to the opening for the lateral shaft **50**, such that the lateral bore **51** now freely communicates with the central bore **12** of housing **11** and the axial bore **42** of sleeve distal portion **44**, as shown in **FIG. 11**. The sleeve distal portion **44** remains disposed in the aorta wall **91** to prevent blood loss through the opening during the vein grafting procedure.

[0014] Preferable vein anchoring means **60** is shown in greater detail in **FIGS. 5 through 7**, and comprises an annular lattice or lattice ring of meshed or woven wire which is secured within the vein **92**. The lattice ring initially occupies a configuration of minimal diameter which is expanded radially to present a larger diameter by action of a balloon catheter **93**. To affix the lattice ring, it is placed onto the deflated head **94** of a balloon catheter **93**, which is inserted into the vein **92** such that the lattice ring is positioned at the end of the vein **92** to be grafted, the body **95** of the catheter extending out the other end of the vein **92**. The balloon head **94** is inflated to expand the lattice radially to embed it into the interior wall of the vein **92**. The vein **92**, with embedded anchor means **60** and the catheter head **94**, is inserted into lateral shaft **50**, with the catheter body **95** extending out through cap **52**, as shown in **FIG. 2**. The anchor means **60** further comprises anchoring prongs **63**, which are connected to the distal end of the lattice ring to extend generally radially outward. The anchoring prongs **63** are sufficiently flexible to allow them to be bent backward against the outer wall of the vein **92** when it is inserted into lateral shaft **50**, yet retain enough elastic memory such that they will resume the radial configuration when not so confined.

[0015] The vein **92** is connected to the aorta wall **91** as shown in **FIGS. 3 through 7**. The circular opening in the aorta wall **91** has been formed by the surgeon first making a small incision and then inserting the punch head **34** through the incision and the aorta wall **91**. Alternatively, the punch head **34** itself may be used to breach the aorta wall **91**. The cutting sleeve assembly **40** is then advanced so that the annular cutting rim **41** slices through the aorta wall **91** in conjunction with the disk-shaped distal end **34***b* of the punch head **34** to remove a circular plug of wall material from the aorta wall **91**. The housing **11** is separated into the distal portion **15** and the proximal portion **14**, and the punch assembly **30** and proximal portion **43** of sleeve **45** are retracted to open the passageway to the lateral bore **51**. The end of the vein **92** is now advanced by pushing the catheter body **95** into the lateral shaft **50**. The catheter head **94**, anchoring means **60** and vein **92** advance into the central bore **12**, through the axial bore **42** of cutting sleeve distal portion **44** into the interior of the aorta wall **91**. When the free ends of the anchoring prongs **63** clear the annular cutting rim **41**, they spring outward to extend radially. The catheter head **94** is retracted slightly such that the prongs **63** abut the interior side of the aorta wall **91**, and is then fully inflated to insure that the lattice ring is securely embedded and maximumly expanded to present the largest possible flow opening through the vein. The catheter head **94** is deflated and withdrawn from the vein **92** and from the lateral shaft **50**. The entire device **100** is then withdrawn from the aorta wall **91**, such that the entire vein **92** passes through the distal end of the device and remains attached to the aorta wall **91**.

[0016] Alternatively to the complete method set forth above where both the anastomosis device **100** and the anchoring means **60** are utilized to secure the vein **92** to the aorta wall **91**, it is contemplated that the device **100** could be used with other methods for securing the vein **92**, such as suturing, stapling or with the use of other types of anchor devices.

[0017] It is understood that equivalents and substitutions for certain elements set forth above may be obvious to hose skilled in the art, and thus the true scope and definition of the invention is to be as set forth in the following claims.

I claim:

1. An anastomosis device for joining a vein graft to an aorta wall, comprising:

means to produce an opening in an aorta wall, said means comprising in combination a punch assembly and a cutting sleeve assembly disposed within a central bore of a housing;

a lateral shaft obliquely connected to said housing, said lateral shaft having a lateral bore communicating with said central bore;

wherein said lateral shaft is adapted to receive a vein graft such that said vein graft may be advanced through said lateral bore, said central bore and said opening in said aorta wall for joining to said aorta wall.

2. The device of claim 1, further comprising means to seal said opening in said aorta wall after said opening is produced and during said advancement of said vein graft in order to prevent loss of blood.

3. The device of claim 2, wherein said cutting sleeve comprises a distal portion and a proximal portion, and wherein said punch assembly and said proximal portion of said cutting sleeve is retractable, and wherein said lateral bore freely communicates with said central bore when said punch assembly and said proximal portion of said cutting sleeve is retracted.

4. The device of claim 3, wherein said punch assembly and said portion of said cutting sleeve retain a portion of said aorta wall removed to create said opening when said punch assembly and said proximal portion of said cutting sleeve are retracted.

5. The device of claim 4, wherein said means to seal said opening in said aorta wall comprises said distal portion of said cutting sleeve.

6. The device of claim 5, said cutting sleeve assembly further comprising means to advance said cutting sleeve relative to said punch assembly for producing said opening in said aorta wall.

7. The device of claim 6, wherein said housing comprises a proximal portion and a distal portion, said proximal portion being separable from said distal portion and retractable in order to retract said punch assembly and said proximal portion of said cutting sleeve.

8. The device of claim 7, said lateral shaft further comprising a cap member adapted to receive a balloon catheter therethrough.

9. An anastomosis device for joining a vein graft to an aorta wall comprising:

an elongated housing comprising a central bore;

an annular cutting sleeve assembly disposed within said central bore, wherein at least a portion of said cutting sleeve assembly is retractable relative to at least a portion of said housing;

a retractable punch assembly disposed within said cutting sleeve assembly, wherein said punch assembly is retractable relative to at least a portion of said housing;

a lateral shaft obliquely joined to said housing and comprising a lateral bore;

wherein said retractable portion of said cutting sleeve assembly and said retractable punch assembly are retractable beyond said lateral bore such that said lateral bore is in communication with said central bore when said retractable portion of said cutting sleeve assembly and said retractable punch assembly are retracted, whereby a vein graft may be advanced through said lateral bore and said central bore.

10. The device of claim 9, said cutting sleeve assembly further comprising a distal portion and a proximal portion, such that only said proximal portion is retractable.

11. The device of claim 10, further comprising means to advance said cutting sleeve assembly relative to said punch assembly.

12. The device of claim 11, said housing further comprising a distal portion and a proximal portion, said proximal portion being separable from said distal portion.

13. The device of claim 12, further comprising a balloon catheter, and wherein said lateral shaft further comprises a cap member adapted to receive said balloon catheter therethrough.

14. A method of performing anastomosis of a vein graft to an aorta wall comprising the steps of:

providing an anastomosis device comprising a punch assembly having a punch head and a cutting sleeve disposed in a central bore, and a lateral shaft having a lateral bore communicating with said central bore, said lateral bore adapted to receive a vein graft;

inserting a vein graft into said lateral bore;

inserting said punch head into said aorta wall;

advancing said cutting sleeve to against said punch head to create an opening in said aorta wall;

retracting said punch head and at least a portion of said cutting sleeve proximally beyond said lateral bore, while leaving a portion of said anastomosis device disposed within said opening to prevent blood loss;

advancing said vein graft through said central bore and into said opening in said aorta wall;

securing said vein graft to said aorta wall; and

removing said anastomosis device from said opening and from said vein graft.

15. The method of claim 14, further comprising providing a balloon catheter within said lateral bore, whereby said vein graft is advanced into said opening by advancing said balloon catheter.

16. The method of claim 15, whereby said step of retracting said punch head and at least a portion of said cutting sleeve proximally beyond said lateral bore is accomplished by separating a proximal portion of said anastomosis device from a distal portion of said anastomosis device.

* * * * *